





CENTER FOR DEVICES AND RADIOLOGICAL HEALTH



<b>MANUFACTURER</b>	RT 22 SOMERVILLE NJ 08876
<b>ACCESS NUMBER</b>	M101751
<b>PRODUCT CODE</b>	
<b>PANEL</b>	DENTAL
<b>REPORT TYPE</b>	SERIOUS INJURY
<b>DATE FDA RECEIVED</b>	02/15/1985
<b>DEVICE CATALOGUE NUMBER</b>	W-31G
<b>EVENT DESCRIPTION TYPE</b>	PRELIMINARY

**EVENT DESCRIPTION**

HOSPITAL EXPERIENCING STAPHYLOCOCCUS INFECTION INCIDENT. FIRM'S PRODUCT FOUND TO BE STERILE WHEN TESTED. SURGEONS HAD BEEN WORKING WITH PRODUCT AND LEAVING IT EXPOSED TO AIR LONGER THAN RECOMMENDED. FIRM CONTACT STATED RECOMMENDATION TO THAT EFFECT IN PRODUCT LABELLING, HOWEVER, HE WAS UNCERTAIN OF EXACT TIME PERIOD STATED.

**CLOSEOUT TEXT**

USER

Center for Devices and Radiological Health / CDRH